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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WINSTON, RANDALL O

ART UNIT PAPER NUMBER

1655

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/622,433

Applicant(s)

NUYEN ET AL.

Examiner

Randall Winston

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 9-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 12-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of receipt and entry of the claims filed on 10/31/2005.

The rejections made under 35 U.S.C. 112, second paragraph, have been overcome by Applicant's amendment.

The rejection made under 35 U.S.C. 102(b) has been overcome by Applicant's amendment.

Examiner acknowledges that claims 9-11 have been withdrawn from consideration.

Claims 1-8, 12-25 and new claims 26-28 will be examined on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 12-28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Crumb et al. (US 6,030,943) in view of Gyory et al. (US 5,883,135).

Applicant argues that Crumb's parenteral formulations are exclusively single solvent-based, not mixed solvent-based formulation (i.e. and/or Crumb discloses a pharmaceutically acceptable carriers are enclosed together in one container and not separately within two containers) as well as there is not teaching or suggestion in Crumb to use delivery or reconstitution media other than water-based media, much less mixed solvent delivery or reconstitution media that include alkanols and water.

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Applicant's arguments, however, are not found persuasive because as the examiner explained in his non final rejection of 06/29/2005, claims 1-8, 12-25 and new claims 26-28 still stand rejected under 35 U.S.C. 103(a) because in line Column 6 lines 16-20, Crumb does not teach a single solvent based formulation but Crumb teaches a pharmaceutical composition may be in form of a container (i.e. a kit is a container and the container described in Crumb is a sterile ampoule) comprising firstly lyophilized didemin preparation comprised of a didemnin (aplidine and/or deydrodidemnin) admixed with a diluent and/or water soluble material (i.e. mannitol) and water secondly a reconstitution solution comprising of water.

Moreover, although Crumb does not expressly teach within his reference that surfactant and/or alkanol are mixed with water within Crumb's reconstitution solution, Crumb does teaches that one of ordinary skill in the art would want to utilize surfactant and/or wetting agents within its pharmaceutical formulation and/or container. Therefore, it would have been obvious to one of ordinary skill in the art to just place the surfactant and/or wetting agents taught within Crumb's reference within Crumb's taught reconstitution solution because surfactants and/or wetting agents are well known in the art to be effective carriers to aid in the administration of an active ingredients to a subject.

Furthermore, because Gyory et al. beneficially teach (see, e.g. column 3 line 5-10 and also in other publication page 1 see Ferber, et. al.) that the claimed active ingredient of alkanol is an effective carrier and/or effective delivery enhancer to aid in the administration of an active ingredient to a subject, it would have been obvious to

one of ordinary skill in the art at the time the invention was made to modify Crumb et al.'s pharmaceutical composition and/or kit to include Gyory et al.' alkanol active ingredient within Crumb's pharmaceutical composition and/or kit because the two combined teachings would create an improved claimed pharmaceutical composition and/or kit for enhance delivery of the pharmaceutical composition's active ingredients to a subject. Furthermore, the adjustment of other conventional working conditions (e.g. the substitution of one functional equivalent alkanol for another, the ranges of each active ingredient and the substitution of one surfactant for the other), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan D. Coe
1-19-06
SUSAN COE
PRIMARY EXAMINER